REMARKS

Status of the Claims

Claims 4, 5 and 11 are pending in the present application. Claims 1-3, 7-10, 12 and 13 are withdrawn from consideration by the Examiner. Claim 6 is cancelled as being redundant to claim 4.

Rejections Withdrawn

The rejection under 35 U.S.C. 102(a) over Kappmeyer et al. has been withdrawn in view of the Declaration.

The rejection under 35 U.S.C. 102(a) over Ikadi et al. has been withdrawn in view of the Declaration.

The rejection under 35 U.S.C. 112, second paragraph, has been withdrawn.

Rejection of Claims 4-6 and 11 Under 35 U.S.C. 102(b) Over Bose (Paragraph 6 of Office Action)

Claims 4-6 and 11 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by Bose et al. for the reasons set forth in paragraph 6 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Claim 4, as amended, relates to an isolated recombinant protein from merozoite of *Babesia caballi*, wherein said protein is expressed in a host cell transformed with a DNA vector into

which cDNA having the nucleotide sequence encoding the amino acid sequence as shown in SEQ ID NO: 2 is incorporated into the DNA vector.

The Examiner indicates that in the absence of evidence to the contrary, the disclosed 48kDa protein of Bose et al. and the claimed protein are the same. Applicants respectfully disagree.

First, Applicants are claiming an isolated and recombinant protein. The disclosed 48kDa protein of Bose et al. is neither isolated nor recombinant. Thus, the Examiner is factually incorrect and therefore there is no prima facie case of anticipation.

Second, the Examiner is basically alleging that Applicants' isolated and recombinant protein is somewhere in the 48kDa band so the invention is inherently anticipated. The Examiner is legally incorrect and therefore there is no prima facie case of inherency or anticipation.

A theory of inherency must be supported by facts and/or technical reasoning that reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy* 17 USPQ2d 1461 (BPAI 1990) (emphasis added).

In order for prior art to anticipate a claimed invention on the ground it is inherently produced in a prior art, the inherency must be certain. *Glaxo, Inc. v. Novopharm Ltd.,* (EDNC

1993) 830 F. Supp 871, 29 USPQ2d 1126; *Ex parte Cyba* (POBA 1966) 155 USPQ 756; *Ex parte McQueen* (POBA 1958) 123 USPQ 37.

The fact that the prior art may inherently have the characteristics of the claimed product is not sufficient. *Ex parte Skinner* (BPAI 1986) 2 USPQ2d 1788. Inherency must be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 666 F2d 578, 212 USPQ 323; *Ex parte Keith et al.* (POBA 1966) 154 USPQ 320. Thus, in the present instance, there is no evidence to support the assertion that the cited art inherently achieves the claimed invention. Accordingly, the Examiner has failed to establish a prima facie case of inherency or anticipation.

Contrary to the Examiner's position, the claimed protein and the protein of Bose et al. are clearly distinct. More specifically, the 48 kDa protein(s) disclosed in the Bose et al. reference is merely one of the bands that were detected by SDS-PAGE and Western blotting and recognized by sera from horses experimentally or field-infected with *Babesia caballi*. However, the 48 kDa protein band disclosed by Bose et al. has not been isolated and purified. Clearly, such a disclosure neither anticipates nor suggests the present invention since it does not follow that the protein(s) in the 48 kDa protein band disclosed by Bose et al. is the claimed protein inherently or otherwise.

Moreover, as discussed below, the teachings of the alleged anticipatory Bose et al. reference actually totally contradicts the Examiner's conclusion. Since the protein(s) of the 48 kDa protein band disclosed by Bose et al. has not been isolated and purified, the polypeptide(s) contained in the Bose et al. 48 kDa band is merely one possible candidate for a potentially improved serological test.

Further, it is equally likely that the 48 kDa protein band disclosed by Bose et al. contains not only a single antigen but also several antigens. Indeed, the authors of Bose et al. support Applicants' position, as follows:

> "Thus, further characterization and purification of B. caballi antigens are required to identify target antigens for an improved enzyme immunoassay." [See Bose et al. Abstract]

Similarly, the authors of Bose et al. support Applicants' position in the last paragraph on page 630, left column, as follows:

> Thus, further characterization of the antigens contained in the 48 and 50 kDa bands is required until a single target antigen for an improved serological test can be identified.

In contrast to the Bose et al. reference, the isolated and recombinant protein of the present invention is well identified by the amino acid sequence, which is clearly described throughout the specification and claims as well as in the

claimed sequence listing. Based on the amino acid sequence determined by the inventors, the recombinant protein of the present invention was prepared by a recombinant DNA technique. As a result, the recombinant protein of the present invention is isolated and purified and accordingly homogenous.

Moreover, even if the 48 kDa protein(s) disclosed in the Bose et al. reference is isolated and purified, the resulting protein(s) will possibly be contaminated with **any substance** from the source of *Babesia caballi*. In contrast, the recombinant protein of the present invention will possibly be contaminated, if any contamination is present, with substances from the host cell from which the recombinant protein is produced. This difference is due to the fact that the protein(s) of the Bose et al. reference is obtained from a natural source whereas the recombinant DNA technique uses a host cell for expression.

Accordingly, Applicants respectfully submit that the recombinant protein of the present invention is clearly distinct from the 48 kDA band protein(s) of the Bose et al. reference. Thus, the rejection under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

Rejection of Claims 4-6 Under 35 U.S.C. 112, First Paragraph (Paragraph 7 of Office Action)

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in paragraph 7 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner agrees that the specification is enabling for the claimed isolated recombinant protein. However, the Examiner's position is that the specification is not enabling for a recombinant protein of SEQ ID NO: 2 with one to several amino acid residues therein being deleted, substituted or added. See the last two paragraphs on page 4 of the Office Action.

In order to expedite allowance of the present application, Applicants have cancelled the phrase "cDNA having the nucleotide sequence encoding the amino acid sequence as shown in SEQ ID NO: 2 with one to several amino acid residues therein being deleted, substituted or added." Accordingly, the rejection of claims 4-6 under 35 U.S.C. 112, first paragraph, for the reasons set forth in paragraph 7 of the Office Action should be withdrawn by the Examiner.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner (Reg. No. 32,181) at the telephone number of the undersigned below, to

conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By 

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